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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
[60Day-15-0020]
Proposed Data Collections Submitted for
Public Comment and Recommendations

The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. To request more information on the below proposed project or to obtain a copy of the information collection plan and instruments, call 404-639-7570 or send comments to Leroy A. Richardson, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email to omb@cdc.gov.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget (OMB) approval. Comments are invited on:

(a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility;

(b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to, or for, a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information. Written comments should be received within 60 days of this notice.

Proposed Project - Coal Workers' Health Surveillance Program

(CWHSP) (OMB Control No. 0920-0020, Expiration Date 2/28/2015) -

Revision - National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

NIOSH would like to submit an Information Collection Request (ICR) to revise the data collection instruments being utilized within the Coal Workers' Health Surveillance Program (CWHSP). On May 1, 2014, the Mine Safety and Health Administration (MSHA) published final rule 30 CFR 70, 71, 72, 75, and 90. The new MSHA rule added surface coal miners, a respiratory health assessment, and spirometry testing for chronic obstructive pulmonary disease (COPD) to the previously mandated chest x-ray examination program. These additions are being referred to as the Expanded CWHSP (an additional component under the current CWHSP).

This request incorporates all components that now fall under the CWHSP. Those components include: Coal Workers' X-ray Surveillance Program (CWXSP), B Reader Program, Enhanced Coal Workers' Health Surveillance Program (ECWHSP), Expanded Coal Workers' Health Surveillance Program, and National Coal Workers' Autopsy Study (NCWAS). The CWHSP is a congressionally-mandated medical examination program for monitoring the health of coal miners and was originally established under the Federal Coal Mine Health and Safety Act of 1969 with all subsequent

amendments (the Act). The Act provides the regulatory authority for the administration of the CWHSP. This Program, which operates in accordance with 42 CFR Part 37, is useful in providing information for protecting the health of miners (whose participation is entirely voluntary), and also in documenting trends and patterns in the prevalence of coal workers' pneumoconiosis ('black lung' disease) among miners employed in U.S. coal mines. The total estimated annualized burden hours of 13,471 is based on the following collection instruments:

- Coal Mine Operator Plan (2.10) and Coal Contractor Plan (2.18) - Under 42 CFR Part 37, every coal operator and coal contractor in the U.S. must submit a plan approximately every 4 years, providing information on how they plan to notify their miners of the opportunity to obtain the medical examination. Completion of this form with all requested information (including a roster of current employees) takes approximately 30 minutes.
- Radiographic Facility Certification Document (2.11) - X-ray facilities seeking NIOSH approval to provide miner radiographs under the CWHSP must complete an approval packet including this form which requires approximately 30 minutes for completion.

- Miner Identification Document (2.9) - Miners who elect to participate in the CWHSP must fill out this document which requires approximately 20 minutes. This document records demographic and occupational history, as well as information required under the regulations in relation to the examinations.
- Chest Radiograph Classification Form (2.8) - NIOSH utilizes a radiographic classification system developed by the International Labour Office (ILO) in the determination of pneumoconiosis among coal miners. Physicians (B Readers) fill out this form regarding their interpretations of the radiographs (each image has two separate interpretations, and approximately 7% of the images require additional interpretations). Based on prior practice it takes the physician approximately 3 minutes per form.
- Physician Application for Certification (2.12) - Physicians taking the B Reader examination are asked to complete this registration form which provides demographic information as well as information regarding their medical practices. It typically takes the physician about 10 minutes to complete this form.
- Guidelines for Spirometry in the ECWHSP Mobile (Internal use, no form number assigned) - Miners (both active and

former) participating in the ECWHSP component of the Program are offered a spirometry test. This form is administered by a NIOSH employee (or contractor) in the ECWHSP Mobile Unit during the initial intake process and takes approximately 5 minutes to complete. This information is required to make sure that the test can be done safely and that the miner is physically capable of performing the spirometry maneuvers.

- Spirometry Facility Certification Document (2.14) - This new form is analogous to the Radiographic Facility Certification Document (2.11) and records the spirometry facility equipment/staffing information. Spirometry facilities seeking NIOSH approval to provide miner spirometry testing under the CWHSP must complete an approval packet which includes this form. It is estimated that it will take approximately 30 minutes for this form to be completed at the facility.
- Respiratory Assessment Form (2.13) - This new form is designed to assess respiratory symptoms and certain medical conditions and risk factors. It is estimated that it will take approximately 5 minutes for this form to be administered to the miner by an employee at the facility.

- Spirometry Results Notification Form (2.15) - This new form will replace previous forms 2.15, 2.16 and 2.17. It is used to: collect information that will allow NIOSH to identify the miner in order to provide notification of the spirometry test results; assure that the test can be done safely; record certain factors that can affect test results; provide documentation that the required components of the spirometry examination have been transmitted to NIOSH for processing; and conduct quality assurance audits and interpretation of results. It is estimated that it will take the facility approximately 20 minutes to complete this form.
- Pathologist Invoice - Under the NCWAS, the invoice submitted by the pathologist must contain a statement that the pathologist is not receiving any other compensation for the autopsy. Each participating pathologist may use their individual invoice as long as this statement is added. It is estimated that only 5 minutes is required for the pathologist to add this statement to the standard invoice that they routinely use.
- Pathologist Report - Under the NCWAS the pathologist must submit information found at autopsy, slides, blocks of tissue, and a final diagnosis indicating presence or

absence of pneumoconiosis. The format of the autopsy reports is variable depending on the pathologist conducting the autopsy. Since an autopsy report is routinely completed by a pathologist, the only additional burden is the specific request for a clinical abstract of terminal illness and final diagnosis relating to pneumoconiosis. Therefore, only 5 minutes of additional burden is estimated for the pathologist's report.

- Consent, Release and History Form (2.6) - This form documents written authorization from the next-of-kin to perform an autopsy on the deceased miner. A minimum of essential information is collected regarding the deceased miner including an occupational history and a smoking history. From past experience, it is estimated that 15 minutes is required for the next-of-kin to complete this form.

As indicated by the below burden table, the total annualized burden hours for this request are 13,471. There are no costs to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden/Response (in hrs)	Total Burden (in hrs)
Coal Mine	2.10	388	1	30/60	194

Operator					
Coal Mine Contractor	2.18	575	1	30/60	288
X-ray Facility Supervisor	2.11	40	1	30/60	20
Coal Miner	2.9	14,560	1	20/60	4,853
B Reader Physician	2.8	31,000	1	3/60	1,550
Physicians taking the B Reader Examination	2.12	100	1	10/60	17
NIOSH employee (or contractor)	Guidelines for Spirometry in the ECWHSP Mobile Unit - No Form # assigned (internal document)	4,560	1	5/60	380
Spirometry Facility Supervisor	2.14	200	1	30/60	100
Spirometry Facility Employee	2.13	14,560	1	5/60	1,213
Spirometry Technician	2.15	14,560	1	20/60	4,853
Pathologist	Invoice --No standard form	5	1	5/60	1
Pathologist	Pathology Report -- No standard form	5	1	5/60	1
Next-of-kin for deceased miner	2.6	5	1	15/60	1
Total					13,471

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